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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,487	08/23/2001	Robert F. Rioux	BSC-187 (1002/257)	1401
21323	7590	08/11/2004	EXAMINER	
TESTA, HURWITZ & THIBEAULT, LLP HIGH STREET TOWER 125 HIGH STREET BOSTON, MA 02110			PELLEGRINO, BRIAN E	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/935,487

Applicant(s)

RIOUX ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-16 is/are pending in the application.
- 4a) Of the above claim(s) 9-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed (5/26/04) in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's AF submission filed on 3/24/04 has been entered.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the recitation that the "spaced windings are separated by a distance in the range of from about 4mm to about 10mm" is not found in the written disclosure. It is noted that this new, narrower range falls within the broader range pointed out by the applicant found in the specification, but this upper limit range was not originally disclosed.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claims 1-4,6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al. (WO 97/27898) in view of Yachia et al. (5246445). Evard et al. illustrates (Fig. 2') a coil segment with a middle portion **14** spaced from the proximal and distal windings and has a diameter less than the proximal and distal ends. Evard et al. disclose a covering or what can be interpreted as "webbing" such that a portion or the entire device is encapsulated or covered by the covering, page 33, lines 5-8. It can be interpreted from the disclosure of Evard on page 14, lines 22-25 that these coverings inhibit ingrowth of body tissue. Evard also discloses the coil can be a biocompatible wire made from steel or nickel titanium, page 34, lines 1-3. Evard additionally discloses that the different features of various embodiments are capable of being combined to form embodiments not shown, page 45, lines 31-36. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. Clearly, the device is capable of being positioned coaxially within the body lumen of a patient. However, Evard does not disclose a cross-sectional area of the wire within the range of 0.0079mm^2 to 7.1mm^2 or separation of the windings within the range of 4mm to 10mm or the use of hooks at each of the proximal and distal ends of the prosthetic device. Yachia et al. teach a cross-sectional area of 0.0079mm^2 to 0.785mm^2 and a separation of the windings with a range 0.5 to about 2mm, col. 4, lines 44,45,49-52. In this instance the prior art recitation of *about* 2mm for the spacings between windings in Yachia can be considered to be about 4mm since the use of "about" is broad and the interpretation can reasonably include a variance of $\pm 2\text{mm}$. See MPEP 2144.05. Yachia et al. also teach (Fig. 1a) a stent with hooks **3** at both the proximal and distal

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ends of the coil body for connection to a delivery system, col. 6, lines 13-16. It would have been obvious to one of ordinary skill in the art to use a wire with the cross-sectional area and spacing distance of 0.5-2mm between windings as taught by Yachia et al. with the device of Evard et al. in order to provide some flexibility by having some distance between windings, but also some greater structural support with the larger cross-sectional area wire. It would also have been obvious to one of ordinary skill in the art to incorporate hooks at both proximal and distal ends of a stent as taught Yachia et al. in the device of Evard et al. such that the vessel apparatus does not dislodge from the instrument used to implant it. The addition of the hooks enables the surgeon to precisely place the vessel-opening device in its location without the apparatus being displaced during insertion.

Claims 7,8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al. (WO 97/27898) in view of Yachia et al. '445 as applied to claim 1 above, and further in view of Hachtman et al. (5645559). Evard et al. as modified by Yachia et al. is explained supra. Evard does disclose that silicone can be used in sleeves placed on stent devices, page 17, lines 21-24. However, Evard as modified by Yachia does not disclose a low durometer silicone within the range of 0-60D. Hachtman et al. also teach that a silicone layer is placed on the stent to provide a barrier that prevents the growth of tissue through the stent and to support the flow of fluid through the lumen, col. 2, lines 14-18. Hachtman et al. also teach that low durometer silicone, such as 30D is placed on a stent, col. 4, lines 49-52. It would have been obvious to one of ordinary skill in the art to use a low durometer silicone as taught by Hachtman et al. for the silicone

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on Evard's vessel apparatus as modified by Yachia such that fluid flow is maintained through the lumen of the device while preventing tissue ingrowth.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard et al. (WO 97/27898) in view of Huxel et al. (6494908). Evard is explained supra. However, Evard does not disclose the separation distance between the windings is of a range of about 4mm to about 10mm. Huxel teaches a stent for body lumens can have a distance between coil windings about 4mm, col. 5, lines 47-51. It would also have been obvious to one of ordinary skill in the art to incorporate the spaced winding of about 4mm taught by Huxel et al. in the implantable device of Evard et al. such that it provides more flexibility in the coil which would enable the device to provide more flexibility in a tortuous area of a vessel lumen.

Response to Arguments

Applicant's arguments filed 5/26/04 have been fully considered but they are not persuasive. Regarding the remarks that Yachia does not include the teaching that the spacings between windings are not about 4mm, the Examiner is not persuaded since Yachia teaches "about 2mm" which can encompass "about 4mm. Please note that in a case where the claimed dimension is overlapped by the prior art disclosure, a prima facie case of obviousness exists, see In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 703-306-5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

TC 3700, AU 3738

Brian Pellegrino

Brian Pellegrino